

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**50-763**

**Microbiology Review(s)**

# **Product Quality Microbiology Review**

## **Review for HFD-150**

**June 19, 2002**

**NDA:** 50-763 resubmission.

### **Drug Product Name**

**Proprietary:** MITOExtra™

**Non-proprietary:** Mitomycin for Injection  
(7-amino-9a-methoxymitosane)

### **Drug Product Classification:**

Antineoplastic

**Review Number:** 2

### **Subject of this Review**

**Submission Date:** 3/20/02

**Receipt Date:** 5/9/02

**Consult Date:** 5/6/02

**Date Assigned for Review:** 6/3/02

### **Applicant/Sponsor**

**Name:** SuperGen, Inc.

**Address:** Two Annabel Lane, Suite 220  
San Ramon, CA 94583

**Representative:** Sam Boddapati, Ph.D.


**Telephone:** 925-560-0100

**Name of Reviewer:** James L. McVey

**Conclusion:** The application is recommended for approval on the basis of product quality microbiology.

---

## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: NA
  2. SUPPLEMENT PROVIDES FOR: NA
  3. MANUFACTURING SITE: 
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:            : Injection, 5 mg/vial.
  5. METHOD(S) OF STERILIZATION: Sterile            processing.
  6. PHARMACOLOGICAL CATEGORY: antineoplastic
- B. SUPPORTING/RELATED DOCUMENTS: Original application Microbiologist's Review dated October 7, 1998.
- C. REMARKS: This is            The drug product has antimicrobial qualities and

filename: 50763r2

## **Executive Summary**

## I. Recommendations

**A. Recommendation on Approvability - Recommended**

**B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – NA.**

## II. Summary of Microbiology Assessments

**A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug product is**

— This is —  
The drug product has antimicrobial qualities and —

**B. Brief Description of Microbiology Deficiencies – None.**

**C. Assessment of Risk Due to Microbiology Deficiencies – None.**

### III. Administrative

**A. Reviewer's Signature** \_\_\_\_\_

### B. Endorsement Block

Microbiologist: J. L. McVey

Microbiology Supervisor: P. H. Cooney

### C. CC Block

**cc:**

DFS

HFD- 805/McVey/50763r2

Redacted 7

pages of trade

secret and/or

confidential

commercial

information

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
James McVey  
7/2/02 11:24:46 AM  
MICROBIOLOGIST

Peter Cooney  
7/2/02 03:35:08 PM  
MICROBIOLOGIST